



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**Note to Reader**  
**January 15, 1998**

**Background:** As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

**Note:** This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket ( RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director  
Special Review and Reregistration Division

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

November 23, 1998

MEMORANDUM

**SUBJECT:** **Phosmet** (List A Reregistration Case No. 0242/Chemical ID No. 059201).  
Revised Product and Residue Chemistry Chapters of the HED RED. No. MRID  
#. DP Barcode No. D250029.

**FROM:** Christina Swartz, Chemist  
Reregistration Branch 1  
Health Effects Division (7509C)

**THROUGH:** Whang Phang, Ph.D., Branch Senior Scientist  
Reregistration Branch 1  
Health Effects Division (7509C)

**TO:** Kathy Monk/Linda Werrell, PM 52  
Reregistration Branch  
Special Review and Reregistration Division (7508W)

The product and residue chemistry considerations for the HED RED chapter and risk assessment for phosmet were summarized in a memorandum dated 6/18/98 (C. Swartz, DP Barcode D247022). In a letter dated 8/20/98, Schering-Plough Animal Health Corporation (SPAH) generally concurred with the Agency's assessment, but also recommended specific changes in the residue chemistry chapter.

**CONCLUSION**

HED concurs with the proposed changes, which are incorporated into the attached revised chapter. The proposed changes do not affect the dietary risk assessment.

**DETAILED CONSIDERATIONS**

The changes proposed by Schering Plough are as follows:

- The registrant for the Del-Phos® Emulsifiable Liquid is Schering-Plough Animal Health Corporation, and not Mallinckrodt Veterinary Inc.
- The correct EPA Registration No. for the Del-Phos® product is 773-76.

- SPAH has removed the dip use from registered labels, and does not wish to reinstate the use at this time.
- EPA recommended SPAH revise labels to specify a maximum of 4 spray applications to cattle at a minimum of 7 day re-treatment interval, and further stated that the directions for a more concentrated solution should be deleted. In addition, a maximum of 3 applications to swine were recommended at a 14-day re-treatment interval. SPAH contends that labels have been revised accordingly, with the exception of the 4-treatments/season maximum; SPAH proposes to make the final change during Phase 5.
- HED stated that conclusions regarding the tolerance reassessment for livestock commodities were contingent upon submission of supporting storage stability data. SPAH states that these data have been submitted to the Agency, and support the reassessed tolerances [footnote 27 of Table B should be revised accordingly].
- SPAH recommended the dip use on beef and non-lactating dairy cattle be removed from the use table, since it is not registered.
- Regarding the need for an additional feeding study in milk [footnote 28 of Table B], the registrant states that the point is moot, since dermal uses on dairy cattle are not registered and are not being pursued at this time. HED intends to leave the comment as is, since an additional feeding study would be used to determine the potential for secondary residues in milk resulting from consumption of treated feed, and not from direct dermal application.
- The CODEX harmonization table contained an error for the reassessed US tolerance for residues in meat, and required a change in the reassessed tolerance for residues in milk.

### *Product Chemistry*

Product chemistry data requirements are satisfied for the Gowan 94% Ts [EPA Reg. Nos. 10163-172 and 10163-227]; additional data are required concerning OPPTS 830.6317 (Storage stability) and 830.7050 (UV/Visible absorption), a new requirement under OPPTS 830 Series, issued 8/96). Provided that the registrant submits these data, and either certifies that the suppliers of beginning materials and the manufacturing process for the phosmet manufacturing use products (MPs) have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of phosmet with respect to product chemistry data requirements.

### *Residue Chemistry*

The residue chemistry database is largely complete (additional data requirements are noted below). The nature of the residue in plants and livestock (via both dermal and oral dosing) is adequately understood; residues of concern include phosmet and its oxon. Phosmet *per se* and phosmet oxon were either not found in plant metabolism studies, or identified at relatively low percentages of the total radioactive residues, with the exception of corn, in which phosmet constituted up to 50% of the fodder radioactivity. In livestock metabolism studies, qualitative and quantitative differences were observed for oral versus dermal dosing. Neither phosmet nor its oxon were identified in ruminants dosed orally, whereas phosmet was identified in all tissues

except fat at low levels via dermal dosing (phosmet *per se* was a major residue in fat via the dermal route). In both oral and dermal dosing, the majority of the residue was comprised of phthalic acid and N-substituted derivatives of phthalimides.

The residue chemistry database is adequate to reassess most tolerances listed in 40 CFR §180.261. Additional data are required to (re)assess tolerances for residues in sweet potato, blueberry, and in cotton gin by-products. The available data are adequate to reassess tolerances for residues in livestock commodities, taking into consideration both consumption of treated feed items and direct dermal application. HED had previously required the registrant to submit a new goat metabolism study, and therefore kept the requirement for a new feeding study reserved. HED later agreed to upgrade the goat metabolism study; in conjunction with the preparation of the HED RED chapters, HED has taken into consideration all the data submitted pertaining to the magnitude of the residue in livestock commodities. These data are adequate to reassess tolerances.

Although additional data could demonstrate that a tolerance for phosmet residues in milk is not required, the available data support a tolerance based on the combined limits of quantitation (LOQs) for phosmet and phosmet oxon. Reassessed tolerances for residues in meat, meat by-products and fat of cattle are based on both consumption of treated feed items and on direct dermal application. Reassessed tolerances for residues in swine are based solely on dermal application (consumption of treated feed items is not considered to contribute to residues in swine). Residues in poultry commodities can be classified under category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues. Therefore, tolerances are not required for phosmet residues in poultry commodities.

The U.S. tolerances are currently harmonized with CODEX with respect to the regulated residues; in addition, reassessed tolerance levels for certain commodities are compatible with CODEX MRLs. However, others cannot be harmonized based on existing use patterns supported through reregistration.

Anticipated residues (ARs) in numerous RACs and milk were generated by HED/CEB2 (D. Hrdy memo dated 7/17/98, DP Barcode No. D247741) for the purpose of dietary exposure/risk assessment; these ARs are based on monitoring data from USDA's pesticide data program (PDP), and on percent crop treated data (%CT) from BEAD (assessment dated 3/5/98, J. Alsadek). Anticipated residues in meat, meat byproducts and fat have been generated in the residue chemistry RED chapter, and are based on dermal application data, since refinements to residues in feed items render the residue contribution from livestock diets insignificant.

Gowan has indicated a desire to support the previously unsupported uses on citrus and sweet corn. Gowan will submit proposed use patterns, and HED will then determine if the uses can be supported, and appropriate reassessed tolerances. The following additional residue chemistry data are required (refer to Table B in the residue chemistry chapter, and on specific guideline discussions for more information):

- label amendments (refer to the discussion under “directions for use”);
  - Representative storage stability studies for phosmet oxon in an oil seed or nut matrix, a starchy vegetable, and a forage crop (partial submission currently under review in HED);
  - Geographically representative residue data for blueberry;
  - Residue data for cotton gin byproducts (a new requirement under OPPTS 860.1500);
- and
- Residue data supporting post-harvest dust application to sweet potato.

A new analytical method used for data collection in livestock commodities may be acceptable for enforcement purposes. HED will forward the method to BEAD/ACL for a method try-out (MTO).

Attachments: Phosmet Product and Residue Chemistry Chapters of the HED RED.

cc: Reviewer, C. Swartz; List A File; SF

CSwartz:RRB1:CM2:Rm732B:703 305 5877:11/13/98

Secondary Review:CLOlinger:11/18/98

RRB1ExpoTeam Review:11/18/98

# PHOSMET

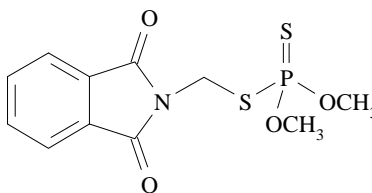
## REREGISTRATION ELIGIBILITY DECISION:

### PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 059201; Case No. 0242

#### DESCRIPTION OF CHEMICAL

Phosmet [N-mercaptomethyl]phthalimide S-(O,O-dimethyl phosphorodithioate) is an organophosphate insecticide registered for use on a variety of vegetables, fruits, and crops.



Empirical Formula:	C <sub>11</sub> H <sub>12</sub> NO <sub>4</sub> PS <sub>2</sub>
Molecular Weight:	317.32
CAS Registry No.:	732-11-6
PC Code:	059201

#### IDENTIFICATION OF ACTIVE INGREDIENT

Technical phosmet is a pink to white crystalline solid with a melting point of 66-69 C. Phosmet is slightly soluble in water (20 mg/L at 20-25 C), more soluble in ethanol and kerosene (<1.0 g/100 mL), and readily soluble in acetone, chloroform, and xylene (>100 g/100 mL).

#### MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/29/97 identified two phosmet MPs registered under PC Code 059201: the Gowan Company 94% Ts (EPA Reg. Nos. 10163-172 and 10163-227). Only the Gowan phosmet MPs are included in HED's conclusions with respect to the adequacy of product chemistry data to support reregistration eligibility of products containing the active ingredient phosmet.

## REGULATORY BACKGROUND

The Science Chapter of the Phosmet Reregistration Standard dated 4/15/86 and the Guidance Document dated 9/86 required additional generic and product-specific product chemistry data for the phosmet MPs. The Phosmet Reregistration Standard Update dated 3/8/90 reviewed data submitted in response to the Reregistration Standard and summarized the product chemistry database in support of the reregistration of phosmet. The Update required additional product chemistry data concerning GLNs 61-1, 61-3, 62-2, and 63-17 (OPPTS 830.1550, 830.1670, 830.1750, and 830.6317) for the phosmet MPs. The phosmet 94% Ts were registered to Stauffer Chemical Co. (EPA Reg. Nos. 476-2178 and 476-2177, respectively) when the Reregistration Standard was issued, and to ICI Americas Inc. (EPA Reg. Nos. 10182-234 and 10182-233, respectively) when the Update was issued.

The current status of the product chemistry data requirements for the phosmet MPs is presented in the attached data summary table.

## CONCLUSIONS

Most pertinent data requirements are satisfied for the Gowan 94% Ts; additional data are required concerning OPPTS 830.6317 (Storage stability) and 830.7050 (UV/Visible absorption, a new requirement under OPPTS 830 Series, issued 8/96). Provided that the registrant submits the data required in the attached data summary tables for the 94% Ts, and either certifies that the suppliers of beginning materials and the manufacturing process for the phosmet MPs have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of phosmet with respect to product chemistry data requirements.

## AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): Addendum to 1919 and 1920  
Subject: Addendum to March 19, 1987 Memo. EPA Registration Nos. 476-2177 and 476-2178 - Phosmet (Imidan<sup>TM</sup>) Registration Standard - Stauffer Initiation of Data Requirements and Request for Time Extensions Dated December 4, 1986 and January 20, 1987.  
From: M. Bradley  
To: G. LaRocca and Toxicology Branch  
Dated: 5/28/87  
MRID(s): None



CBRS No(s).: 2628  
Subject: Stauffer Chemical Company Response to the Product Chemistry Chapter of the Phosmet Registration Standard.  
From: G. Makhijani  
To: G. LaRocca/A. Heyward and A. Rispin  
Dated: 9/29/87  
MRID(s): 40274801

CBRS No(s).: 10653  
DP Barcode(s): D183032  
Subject: Phosmet Reregistration. Product Chemistry Guidelines 63-14 to 63-18 and 63-20.  
From: A. Aikens  
To: L. Schnaubelt/B. Lowery  
Dated: 11/19/92  
MRID(s): 41909901

CBRS No(s).: None: RD Memorandum  
DP Barcode(s): None  
Subject: Product Chemistry Review on Phosmet.  
From: I. Gairola  
To: A. Heyward  
Dated: 4/14/93  
MRID(s): 40510801 and 40510802

CBRS No(s).: None: RD Memorandum  
DP Barcode(s): D221906  
Subject: Product Chemistry Review of Imidan Technical Organophosphorus Insecticide.  
From: S. Malak  
To: G. LaRocca/A. Heyward  
Dated: 3/7/96  
MRID(s): 43868001 and 43868002

## PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

### References (cited):

00075996 Stauffer Chemical Company (1975) [Chemistry of Imidan/Prolate]. (Compilation; unpublished study received Apr 20, 1976 under 476-2167; CDL:231210-A)

00112263 Stauffer Chemical Co. (1965) [Chemical Study: Imidan]. (Compilation; unpublished study received Jun 22, 1966 under 6G0506; CDL: 092792-A)

00112314 Zoecon Industries, Inc. (1978) Zoecon 1% Phosmet Dust for Control of Hog Lice. (Compilation; unpublished study received Sep 7, 1978 under 2724-EX-14; CDL:235049-A)

00112317 Stauffer Chemical Co. (1976) [Chemical Study: Imidan Technical]: Project No. 149625. (Compilation; unpublished study received Nov 16, 1976 under 476-2178; CDL:227419-A)

00126567 Zoecon Industries, Inc. (1983) Chemistry Data: Zoecon RF-224 Phosmet Flowable for Control of Scabies Mite, Cattle Lice and Hornflies. (Compilation; unpublished study received Mar 3, 1983 under 2724-EX-31; CDL:249788-A)

40274801 Myers, H. (1987) Phosmet - Physical Properties: Laboratory Project ID: RRC 87-67. Unpublished study prepared by Stauffer Chemical Co. 64 p.

40344401 Riggs, R. (1987) Phosmet - The Vapor Pressure, Aqueous Solubility and Octanol/Water Partition Coefficient: Laboratory Project ID RRC 87-64. Unpublished study prepared by Stauffer Chemical Co. 28 p.

40510801 Kahn, B. (1987) Analysis and Certification of Product Ingredients in Imidan Insecticide and Prolate Livestock Insecticide: Proj. ID RRC-87-122. Unpublished study prepared by Stauffer Chemical Co. 281 p.

40510802 Javdani, K. (1988) Description of Beginning Materials and Manufacturing Process and Discussion of the Formation of Impurities for Imidan/Prolate Technical: RRC No. 88-1. Unpublished study prepared by Stauffer Chemical Co., Richmond Research Center. 68 p.

41909901 Eya, B. (1991) Phosmet - Physical and Chemical Properties: Lab Project Number: ENV-037. Unpublished study prepared by ICI Americas Inc., Western Research Ctr. 26 p.

43868001 Clark, A. (1995) Product Chemistry for Phosmet (O,O-Dimethyl-S-phthalimidomethyl Phosphorodithioate), Series 62 - Analysis and Certification of Product Ingredients: Lab Project Number: 3788-01. Unpublished study prepared by Midwest Research Institute. 99 p.

43868002 Codrea, E. (1995) Product Chemistry for Phosmet (O,O-Dimethyl S-phthalimidomethyl Phosphorodithioate): Product Identity: Manufacturing Process: Discussion of Impurities. Unpublished study prepared by Gowan Co. 34 p.

Case No. 0242  
Chemical No. 059201

Case Name: Phosmet  
Registrant: Gowan Company  
Product(s): 94% Ts (EPA Reg. Nos. 10163-172 and 10163-227)

#### PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>1</sup>	MRID Number <sup>2</sup>
830.1550	Product identity and composition	Y	<b>40510801</b> <sup>3</sup> , 43868002 <sup>4</sup>
830.1600	Description of materials used to produce the product	Y	<u>00075996</u> , <u>00112317</u> , <b>40510802</b> , 43868002 <sup>4</sup>
830.1620	Description of production process		
830.1670	Discussion of formation of impurities	Y	<b>40510802</b> <sup>3</sup> , 43868002 <sup>4</sup>
830.1700	Preliminary analysis	Y	<b>40510801</b> , 43868001 <sup>4</sup>
830.1750	Certified limits	Y	<b>40510801</b> <sup>3</sup> , 43868001 <sup>4</sup>
830.1800	Enforcement analytical methods	Y	<u>00112263</u> , <u>00112314</u> , <u>00112317</u> , <u>00126567</u> , <b>40510801</b> , 43868001 <sup>4</sup>
830.6302	Color	Y	40274801 <sup>5</sup>
830.6303	Physical state	Y	40274801 <sup>5</sup>
830.6304	Odor	Y	40274801 <sup>5</sup>
830.6313	Stability	Y	40274801 <sup>5</sup>
830.6314	Oxidation/reduction; chemical incompatibility	Y	41909901 <sup>6</sup>
830.6315	Flammability	N/A <sup>7</sup>	
830.6316	Explosibility	Y	41909901 <sup>6</sup>
830.6317	Storage Stability	N <sup>8</sup>	41909901 <sup>6</sup>
830.6319	Miscibility	N/A <sup>7</sup>	
830.6320	Corrosion Characteristics	Y	41909901 <sup>6</sup>
830.7000	pH	Y	40274801 <sup>5</sup>
830.7050	UV/visible Absorption	N <sup>9</sup>	
830.7100	Viscosity	N/A <sup>7</sup>	
830.7200	Melting point/melting range	Y	40274801 <sup>5</sup>
830.7220	Boiling point/boiling range	N/A <sup>7</sup>	
830.7300	Density/relative density/bulk density	Y	40274801 <sup>5</sup>
830.7370	Dissociation constant in water	N/A <sup>10</sup>	
830.7550	Partition coefficient ( <i>n</i> -octanol/water), shake flask method	Y	<u>No MRID no.</u> <sup>11</sup> , <b>40344401</b>
830.7840	Solubility, shake flask method	Y	40274801 <sup>5</sup> , <b>40344401</b>
830.7950	Vapor pressure	Y	<b>40344401</b>

<sup>1</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>2</sup> **Bolded** references were reviewed in the Phosmet Reregistration Standard Update dated 3/8/90; underlined references were reviewed in the Phosmet Reregistration Standard dated 4/15/86; and all other references were reviewed as noted.

<sup>3</sup> These data were also reviewed by the Registration Division (RD Memorandum, 4/14/93, I. Gairola) and were determined to be adequate.

<sup>4</sup> RD Memorandum, D221906, 3/7/96, S. Malak; these data pertain to an alternate formulation of EPA Reg. No. 10163-172.

<sup>5</sup> CBRS No. 2628, 9/29/87, G. Makhijani.

<sup>6</sup> CBRS No. 10653, D183032, 11/19/92, A. Aikens.

<sup>7</sup> Data are not required because the T/TGAIs are solids at room temperature.

<sup>8</sup> The storage container used during the available study was glass; the registrant must submit data reflecting the stability of the product when stored for up to one year in the typical commercial packaging.

<sup>9</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>10</sup> Data are not required because the TGAIs are not acids or bases (Addendum to CBRS Nos. 1919 and 1920, 5/28/87, M. Bradley).

<sup>11</sup> CBRS Memorandum, 2/14/85, A. Reiter.

# Phosmet

## REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 059201; Case 0242

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# PHOSMET

## REREGISTRATION ELIGIBILITY DOCUMENT

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 059201; Case 0242

#### INTRODUCTION

Phosmet, *N*-(mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) is an organophosphate insecticide registered for use on a variety of fruits, vegetables, and field crops, and for direct application to cattle and swine (see Table A). Phosmet is sold in the U.S. by Gowan Company, the basic producer, under the trade name Imidan®. Formulations registered by the basic producers for use on food/feed crops include wettable powder (WP) and dust (D) formulations. Phosmet may be applied to crops using aerial and ground equipment via foliar, dormant, and delayed dormant treatments. Schering-Plough Animal Health Corporation markets the 1 lb/gal EC formulation Del-Phos® for dermal treatment of livestock via spray and backrubber application.

#### REGULATORY BACKGROUND

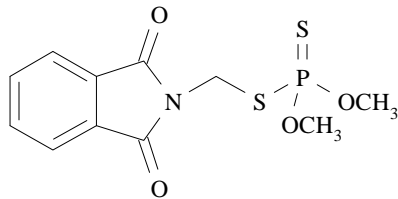
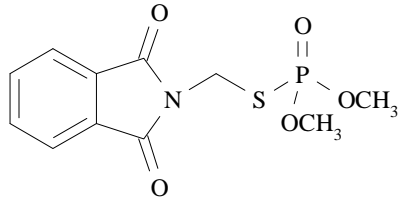
Phosmet is a list A reregistration chemical that was the subject of a Reregistration Standard issued on 4/15/86 and a Guidance Document issued 9/86. The Phosmet Reregistration Standard Update (3/8/90) reviewed residue chemistry data submitted in response to the 9/86 Guidance Document, summarized regulatory conclusions on the available data, and specified that additional data were required for reregistration purposes. Additional data have been received since the Update was issued. The information contained in this document outlines the current residue chemistry science assessments with respect to the reregistration eligibility of products containing the active ingredient phosmet.

Tolerances for the combined residues of phosmet and its oxygen analog, *N*-(mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorothioate) in raw agricultural commodities (RACs) have been established under 40 CFR §180.261 (a) and (b). These tolerances range from 0.1 ppm for residues in nuts, potatoes, and cottonseed to 40 ppm for residues in alfalfa. No tolerances have been established for phosmet residues in processed food/feed commodities.

The HED Metabolism Committee (8/11/95) determined that the residues of concern (i.e. those to be included in the tolerance expression) are phosmet and its oxygen analog. The chemical names and structures of these compounds are depicted in Figure 1.

The Agency has updated the Livestock Feeds Table [Table 1 in the Residue Chemistry Test Guidelines, OPPTS Series 860.1000, August 1996]. Additional residue data are now required for some commodities as a result of changes in Table 1; these data requirements have been incorporated into this document. These new data requirements will be imposed at the issuance of the Phosmet RED but should not affect the reregistration eligibility decision for phosmet. The need for additional tolerances and for revisions to exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

Figure 1. Phosmet and its oxygen analog.

Chemical name <b>Common name/abbreviation</b>	Structure
<i>N</i> -(mercaptomethyl) phthalimide <i>S</i> -( <i>O,O</i> -dimethyl phosphorodithioate)  <b>Phosmet</b>	
<i>N</i> -(mercaptomethyl) phthalimide <i>S</i> -( <i>O,O</i> -dimethyl phosphorothioate)  <b>Phosmet oxygen analog</b>	



## SUMMARY OF SCIENCE FINDINGS

### OPPTS GLN 860.1200: Directions for Use

A search of REFS conducted 5/29/97 identified 5 phosmet end-use products with food/feed uses that are currently registered to Gowan Co (EPA Reg Nos. 10163-##) and Schering-Plough Animal Health Corporation. (EPA Reg No 773-76). These products are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
773-76	11/96	1 lb/gal EC	Del-Phos®
10163-166 <sup>a</sup>	2/95	50% WP	Imidan® 50-WP
10163-168	12/93	5% D	Imidan® 5 Dust
10163-169 <sup>b</sup>	6/96	70% WP	Imidan® 70-WP
10163-175	2/95	50% WP	Imidan® 50-WSB
10163-184 <sup>c</sup>	2/96	70% WP	Imidan® 70-WSB

<sup>a</sup> Includes SLN Nos. AR920001, CA790058, GA920001, IL930002, MI910007, OR910002, OR920008, SC920004, WA920029

<sup>b</sup> Includes SLN Nos. AR930007, AR970001, AR960002, GA940009, GA960004, IL930005, IL960001, MI930006, MS950010, MS960003, NC950009, OR940043, OR94049, SC950004, WA95001.

<sup>c</sup> Includes EPA SLN Nos. AL950002, AL970002, AR950001, AR960001, GA950002, GA960003, IL950002, LA950008, MI950002, MS960004, MS950011, OR940044, OR940050, SC950003, SC950004, TN950005, WA950016.

A review of these labels and supporting residue data indicate that label amendments are required for some use patterns. The label directions for each crop must include a maximum single and seasonal use rate and a minimum allowable PHI. Maximum seasonal rates can be given as either the maximum number of applications allowed per season or as the maximum amount (lb ai/A) of phosmet allowed per season. Both the maximum use rates and the PHIs must be supported by the available residue data.

The registrant must add crop rotation intervals to phosmet labels. HED has recommended in favor of the registrant's proposal to specify a 30-day crop rotation interval for all crops.

There are numerous 24 (c) labels bearing plant-bed use on sweet potatoes, representing the major U.S. production regions. HED has determined that the existing data on potato can be translated to support this use. Therefore, the plant bed use should be added to the Federal labels and the 24 (c) uses should be canceled.

Phosmet labels specifying application to blueberry include a restriction to the northeastern U.S. Numerous 24 (c) registrations allow phosmet use on blueberry in other regions, although there are no supporting residue data from these regions (e.g., MI, WA and OR, and NC). The 24 (c)

registrations for uses on blueberry should be canceled. The registrant must submit residue data from the additional regions and subsequently propose lifting the geographic restriction from the Federal labels.

The label for the Del-Phos® 1 lb/gal EC must be modified to specify a maximum of four spray applications to cattle at a minimum 7-day re-treatment interval.

A comprehensive summary of the registered feed/food use patterns for phosmet, based on the product labels registered to Gowan Co. and Schering-Plough Animal Health Corporation, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of phosmet is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of phosmet food/feed uses are based on the use patterns registered by the basic producer, Gowan Co., and to Schering-Plough Animal Health Corporation. When end-use product DAIS are developed (e.g., at issuance of the RED), RD should require that all EP labels [e.g., multiple active ingredient (MAN) labels, SANS, and products subject to the generic data exemption] be amended such that they are consistent with the basic producers' labels.

Recently the registrant Gowan Co. expressed the desire to reinstate uses on citrus fruits and sweet corn; however, since no formal proposal has been submitted for review, these crops are not included in Table A.

#### OPPTS GLN 860.1300: Nature of the Residue in Plants

Metabolism studies conducted on cherry, potato and corn have been submitted to the Agency. In the potato metabolism study, neither phosmet nor phosmet oxon were identified in tubers from potato plants treated foliarly 4 times at 1-2X the maximum label rate, with a 7-day PHI; the total radioactive residue (TRR) in mature potato tubers was approximately 2 ppm. In the corn metabolism study, the highest TRR was found in fodder (>200 ppm), and the lowest TRR was found in grain (~4 ppm); phosmet was identified at approximately 24% of the forage TRR, 27% of the cob TRR, and 53% of the fodder TRR, but was not identified in grain. Phosmet oxon was not identified in corn matrices [2 applications were made at 0.9 to 1.0 lb ai/A, with 62 days between applications]. In the cherry metabolism study, TRRs in cherries treated at 7X the maximum label rate were 34 and 22 ppm at PHIs of 7 and 14 days, respectively; phosmet was identified at a maximum of approximately 9 %TRR, and phosmet oxon was identified at a maximum of approximately 7 %TRR.

The Agency previously concluded that data should be generated for the metabolite phthalimide, which was believed to be of toxicological concern. However, the Agency later reversed this decision, and no residue data for phthalimide are required; The HED Metabolism Committee (M. Metzger, 8/11/95) has concluded that the residues of concern in plants include phosmet and its oxygen analog. Regulation of the metabolite phthalimide is not required.

## OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in poultry is understood based on an adequate metabolism study conducted in laying hens. Hens were dosed with radiolabeled phosmet for 7 days at 10.5 ppm in the diet (equivalent to 2.5X the maximum theoretical dietary burden, based on reassessed tolerances). Radioactive residues plateaued in egg yolk and whites on days 6 and 3, respectively. Total radioactive residues (TRRs) were 0.04 ppm in egg yolk, 0.006 ppm in egg white, 0.02 ppm in breast muscle (meat), 0.01 ppm in thigh muscle (meat), 0.24 ppm in liver, 0.21 ppm in kidney, and 0.005 ppm in fat. Phosmet was identified only in egg yolk, at 3.1 %TRR (0.001 ppm). Phosmet oxon was not identified in any poultry matrix [total identified radioactivity ranged from 45 to 85 %TRR]. Radioactive residues consisted primarily of phthalic acid and N-substituted derivatives of phthalimides.

The nature of the residue in ruminants is adequately understood, based on a ruminant metabolism study in which dairy cattle were dosed with radiolabeled phosmet for 4 days at 8.8 ppm in the diet (equivalent to 0.2X the maximum theoretical dietary burden, based on reassessed tolerances; HED notes that the dosing level used in the study was not adequate, although HED agreed to accept the results of the study, and waived the requirement for a new ruminant metabolism study). Radioactive residues plateaued in milk on day 3, at 0.014 ppm. Total radioactivity was 0.2 ppm in liver, 0.24 ppm in kidney, 0.14 ppm in muscle (meat), and 0.006 ppm in fat. Neither phosmet nor its oxon were detected in any ruminant matrices [total identified radioactivity ranged from 14 to 54 %TRR]. Radioactive residues consisted primarily of phthalic acid and N-substituted derivatives of phthalimides.

Adequate metabolism studies reflecting the nature of the residue following dermal application to cattle and swine have been submitted. In cattle, total radioactive residues (TRR) ranged from 1.37 ppm in muscle to 9.39 ppm in kidney sacrificed within 24 hours of dosing, and ranged from 1.42 ppm in omental fat to 3.96 ppm in kidney following sacrifice within 72 hours of dosing. In cattle, 76.7-96.0% of the TRR was identified or characterized as phosmet *per se*, N-substituted phthalimides, or partially characterized unknowns. Phosmet was a minor component of every tissue except fat, where it constituted almost all of the radioactivity. Phosmet oxygen analog (oxon) was not detected in any tissue. Desmethylphosmet was identified at approximately 9 %TRR in liver, and 4 %TRR in kidney.

Total radioactive residues in swine ranged from 0.159 ppm in fat to 1.08 ppm in liver. The urine was the primary route of elimination. Phosmet *per se* constituted >80% of the TRR in fat, and 17.4, 1.1, and 1.3% TRR (0.014, 0.006, and 0.008 ppm), respectively, in muscle, kidney, and liver. Desmethylphosmet constituted 3.5 %TRR in kidney and 0.8 %TRR in liver.

The nature of the residue in livestock is adequately understood, based on dermal and oral metabolism studies submitted in support of reregistration. The studies demonstrate that although qualitative and quantitative differences are observed in oral and dermal livestock metabolism studies, the principle residues of toxicological concern are phosmet and its oxon

(desmethylphosmet is not expected to have significant anticholinesterase activity due to loss of the methyl group, and therefore need not be included in the tolerance expression).

#### OPPTS GLN 860.1340: Residue Analytical Methods

The Pesticide Analytical Manual (PAM), Vol. II lists a gas chromatography method with flame photometric detection (GC/FPD) and a GC method with flame ionization detection (GC/FID) as Methods II and III, respectively, for tolerance enforcement.

A revised GC flame photometric detection method has been used to collect data from recent magnitude of the residue studies reflecting dermal treatment of livestock. The new method, in contrast to the PAM II methods, replaces benzene with a safer solvent mixture, uses smaller sample weights and extraction volumes, has a lower limit of quantitation (LOQ), and eliminates interferences that necessitate use of a sulfur-mode detector in the PAM method. This new method is a good candidate to replace the existing PAM, Vol. II methods for enforcement of tolerances for residues in livestock commodities, and will be forwarded to BEAD/ACL for an Agency MTO.

#### OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that phosmet is completely recovered using FDA Multiresidue Protocols PAM I Section 302, but is not recovered using Sec. 303. Phosmet oxygen analog is not recovered by PAM I Secs. 303 or 304.

#### OPPTS GLN 860.1380: Storage Stability Data

Data reviewed in the Reregistration Standard Update indicate that phosmet *per se* is stable for 2 years in alfalfa and for 1 year in almond, apple, sweet corn (ear), pepper, potato, soybean, and wheat straw. At storage intervals of 2.5-3 years, phosmet residues declined by 46-56% in corn ear, pepper, and potato; 26% in wheat straw; and 22% in apple. Data reviewed in the Update indicate that phosmet is stable in beef fat for 1 year, in beef liver, kidney, and milk for 6 months, and in muscle for 1 month. Phosmet was stable in eggs for 1 year. Phosmet oxon was stable for 3 months in beef fat, 6 months in milk, and 1 month in beef muscle. The oxon was labile in beef kidney and liver; residues declined to 47 and 13% of fortified levels in beef kidney and liver, respectively, within 5 hours. Additional data submitted by the registrant indicated that phosmet is somewhat labile in kidney and liver; phosmet oxon is very labile in these matrices. Livestock feeding and dermal application studies are supported by adequate storage stability data. Due to the lability of phosmet oxon and phosmet in livestock liver and kidney, HED does not expect significant residues in these matrices. The results of the magnitude of the residue studies support

this conclusion; tolerances for residues in these commodities have been reassessed at the combined limits of quantitation.

Data are also available to indicate that phosmet and phosmet oxon are stable in apple, apple juice, and apple pomace for at least 3 years. Phosmet and phosmet oxon are stable in applesauce, peach, and canned peach for 2 years. Residues declined in peach and canned peach after 2 years.

With the exception of apple and peach matrices, no storage stability data exist for phosmet oxon to support the results of plant magnitude of the residue studies. Storage stability data on phosmet oxon must be submitted for representative crop matrices stored under conditions and intervals which reflect those incurred in residue studies submitted in support of tolerances. The peach and apple storage stability data are representative of fruit crops with established tolerances. Additional representative storage stability studies should be conducted using an oil seed or nut matrix, a starchy vegetable, and a forage crop.

#### OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Provided the registrants make the required label amendments and submit adequate storage stability data, reregistration requirements for magnitude of the residue in plants are fulfilled for the following crops: alfalfa, almond, apple, apricot, cherry, cottonseed, crabapple, grape, kiwifruit, nectarine, peach, pear, pea, pistachio, plum, potato, and nut crops. Adequate field trial data depicting phosmet residues following applications made according to the maximum or proposed federally registered use patterns have been submitted for these commodities. Geographic representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

For purposes of reregistration, residue data on phosmet and phosmet oxon are required for the following commodities: blueberry, cotton gin byproducts, and sweet potato. Although several SLN labels allow the use of phosmet on blueberry in areas outside the northeastern U.S., there are no residue data to support these uses; additional data are required. Although one study was submitted in support of the use of the dust formulation as a post-harvest application to sweet potato, the data cannot be used either for tolerance reassessment or dietary exposure/risk assessment, due to significant GLP violations which compromised the integrity of the study results. Residue data depicting the magnitude of the residue in cotton gin byproducts are now required, due to identification of cotton gin byproducts as a significant livestock feed item; this is a new data requirement [refer to 860.1000, Table 1].

#### OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

Reregistration data requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apple, cottonseed, grape, plum, and potato. Residues concentrated only in cottonseed oil at 2X, in a study in which cotton was treated at ~1X (the study was reviewed initially in the 1986 Reregistration Standard). A tolerance (0.2 ppm) is required for residues in refined cottonseed oil.

#### OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration data requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled based on the data summarized in the Reg. Std. Update, and data submitted since the Update. Based upon the established or reassessed tolerances for phosmet residues in livestock feed items, the calculated theoretical dietary burdens for livestock are presented below:

Feed Commodity	% Dry Matter <sup>a</sup>	% Diet <sup>a</sup>	Tolerance (ppm) <sup>b</sup>	Dietary Contribution (ppm) <sup>c</sup>
<b>Beef Cattle</b>				
Alfalfa forage	35	70	20	40
Cotton, seed	88	10	0.1	0.01
Pea seed	90	20	0.5	0.11
TOTAL BURDEN		100		40.12
<b>Dairy Cattle</b>				
Alfalfa forage	35	60	20	34.29
Cotton, seed	88	20	0.1	0.01
Pea seed	90	20	0.5	0.11
TOTAL BURDEN		100		34.41
<b>Poultry</b>				
Alfalfa meal		10	40	4.0
Cotton seed, meal		20	0.1	0.02
Pea seed		20	0.5	0.1
Corn grain		50	0	0
TOTAL BURDEN		100		4.12

<sup>a</sup> Table 1, OPPTS GLN 860.1000.

<sup>b</sup> Established or reassessed tolerances from Table C.

<sup>c</sup> Contribution = [tolerance / %DM (if cattle)] X % diet, where DM = dry matter.

Based on reassessed tolerances for feed items and on information summarized in Table 1 of OPPTS GLN 860.1000, the maximum theoretical dietary exposure of beef cattle to phosmet is approximately 40 ppm, primarily due to residues in alfalfa forage; the maximum theoretical dietary burden for dairy cattle is approximately 34 ppm, also due primarily to residues in alfalfa forage.

Data discussed in the 1986 Residue Chemistry Chapter indicate that combined residues of phosmet and phosmet oxon were <0.24 ppm in meat, fat, and meat byproducts from cattle dosed for 3 weeks at 20, 45, or 100 ppm [the 20 ppm feeding level was increased to 200 ppm after two weeks]. These dosing levels correspond to 0.5X, 1.1X, 2.5X, and 5X the maximum theoretical dietary burden for beef cattle, and 0.6X, 1.3X, 2.9X and 5.9X the maximum theoretical dietary burden for dairy cattle. In 54 milk samples collected during the study, phosmet and oxon residues were <0.05 ppm (the limit of quantitation, using the phosphomolybdate method).

In another study summarized in the 1986 Residue Chemistry Chapter, phosmet residues were <0.002 ppm in milk from cows dosed at 6.6 ppm (<0.2X the maximum theoretical dietary burden for dairy cattle). The available metabolism and feeding study data indicate that based on the registered use patterns, residues of phosmet and its oxon in milk are anticipated to be below the limit of quantitation (0.05 ppm). Monitoring data have been generated for phosmet *per se* in milk by USDA's Pesticide Data Program (PDP); residues were nondetectable (<0.002 - <0.003 ppm) in 202 milk samples. It is possible that residues in milk could be classified under category 3 of 40 CFR §180.6(a); however, HED cannot make this determination because none of the available feeding studies incorporated a 10X dosing level. Therefore, HED concludes that a tolerance of 0.1 ppm [for combined residues of phosmet and phosmet oxon at the limit of quantitation (LOQ) of 0.05 ppm] should be established for residues in milk.

The existing feeding studies may be re-evaluated with respect to the tolerances for residues in fat, meat, and meat byproducts, now that HED has concluded the nature of the residue is adequately understood, and that residues of concern include phosmet and phosmet oxon. In the study in which cows were dosed at 20/200, 45 and 100 ppm in the diet, the following residues were found in cattle sacrificed within 24 hours of the final dose:

Cattle Feeding Study (Summarized in Reg. Std., MRID No. 00078570): Residues in Tissues from 3 Dosing Levels.\*

Dosing Level (ppm)	Subcutaneous Fat (ppm)	Perirenal Fat (ppm)	Omental Fat (ppm)	Liver (ppm)	Kidney (ppm)	Muscle [meat], (ppm)
45 (1.1X)	0.05	0.09	0.00	0.00	0.02	0.05
100 (2.5X)	0.03	0.04	0.19	0.00	0.01	0.01
20/200 (.5X/5X)	0.03	0.02	0.04	0.00	0.02	0.03

\* Residues are reported as "apparent" combined residues of the parent and oxygen analog (i.e., corrected for concurrent recoveries; hence, the "0" values). All of the above values should properly be reported as <0.05 ppm.

Based on these data, HED can reassess the tolerances for residues in meat, meat byproducts and fat based on a maximum theoretical dietary burden of approximately 40 ppm. A tolerance of 0.1 ppm for residues in meat and meat by-products is appropriately derived from the LOQ for both the parent and the oxon (0.05 ppm); this tolerance is adequate to cover residues derived from dermal application. A tolerance of 0.2 ppm for residues in fat is based on combined dermal and oral residues (see discussion of dermal magnitude studies, below). Since products containing phosmet are not registered for dermal application to goats, horses and sheep, tolerances of 0.1 ppm are adequate for meat, meat byproducts and fat of goats, horses and sheep.

HED conclusions regarding tolerance reassessment for residues in milk, meat, fat and meat byproducts are contingent upon the registrant reporting details of sample storage in these studies, including intervals and conditions.

Acceptable studies have been submitted and reviewed concerning residues in tissues of cattle and swine following dermal treatment. The registrant must amend the Del-Phos® 1 lb/gal EC product label to reflect a maximum of four spray treatments per year, with a 7-day re-treatment interval (refer to discussion under “Directions for Use”).

Combined residues of phosmet and phosmet oxon were <0.043 ppm in fat, <0.036 ppm in muscle, and <0.04 ppm in liver and kidney from cattle slaughtered 3 days following the last of four spray applications of the 1 lb/gal EC formulation at a dilution of 1:90 (~1x); a slightly exaggerated rate was used to account for residues resulting from the back rubber use. The revised tolerances for residues in meat, meat byproducts and fat, reflect both secondary residues from feed and direct dermal application.

In swine treated at a 1:100 dilution, combined residues were <0.04 ppm in liver, kidney, and muscle, and <0.124 ppm in fat from animals at the 1-day PSI. These data indicated that tolerances for residues in hog meat byproducts and meat should be set at the combined LOQ of 0.04 ppm for phosmet and phosmet oxon. The existing tolerance of 0.2 ppm for residues in hog fat is supported by the more recent residue data. Note that tolerances for residues in hog commodities are based solely on dermal use; since the majority of the maximum dietary burden for ruminants is due to alfalfa forage, and since alfalfa forage is not a feed item for swine, direct translation of ruminant commodity tolerances to hog commodities is not appropriate.

Based on reassessed tolerances for residues in poultry feed items and on information summarized in Table 1 of OPPTS GLN 860.1000, the maximum theoretical dietary exposure to poultry is approximately 4 ppm, due primarily to residues in alfalfa meal. A study reviewed in the 1986 Residue Chemistry Chapter indicated that no quantifiable phosmet or oxon residues were detected in fat (<0.05 ppm), muscle (0.04 ppm), or eggs (<0.08 ppm) from hens dosed with phosmet at 50 and 250 ppm (12 and 63x). Tolerances for residues of phosmet and its oxygen analog in poultry tissues and eggs are not required; residues in poultry commodities can be classified under category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues.



OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, and Irrigated Crops  
OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Phosmet is presently not registered for direct use on potable water, aquatic food and feed crops, or in food handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

A confined rotational crop study was submitted and reviewed by the Agency. Based on the submitted data and on additional information subsequently provided to the Agency, HED concludes that registered labels must specify a 30-day plantback interval (PBI) for all crops.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

Based on acceptable confined rotational crop data, limited field rotational crop studies are not required.

TABLE A. PHOSMET USES ON FOOD AND FEED SITES

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
Food/Feed Crops					
Alfalfa					
Broadcast foliar ground, aerial equipment chemigation	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	0.9	1 per cutting	N/A	(except AZ, CA, NV) 7-day PHI/pregrazing interval (PGI) Do not apply during bloom period
AZ, CA, NV only		0.7			14-day PHI/PGI
Almond					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-184]	3.0	1	N/A	30-day PHI
CA only	70% WP [10163-169]	3.7	2	NS	30-day PHI
Apple					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	4.0	6	NS	7-day PHI A maximum of 21 lb ai/A/season may be applied

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
<b>Apricots</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	3.0	NS	NS	14-day PHI
<b>Blueberry</b>					
Broadcast foliar ground, aerial equipment	50% WP <sup>a</sup> [10163-166] [10163-175] 70% WP <sup>b</sup> [10163-169] [10163-184]	1.0	2	NS	3-day PHI
<b>Cherry (tart/sour)</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	1.75	NS	NS	7-day PHI

TABLE A. continued

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
<b>Cherry (sweet)</b>					
Broadcast foliar ground, aerial equipment	50% WP [OR910002] 70% WP [OR940049] [OR940050]	1.0	NS	NS	Applications are made prior to shuck fall.
<b>Cotton</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	1.0	10	3	21-day PHI Do not apply in Copiah and Clairborne counties, MS; Lauderdale and Madison counties, AL; and Lawrance county, TN Do not apply within 1 mile of estuarine waters nor within 100 feet of aquatic habitats
<b>Crabapple</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	4.0	6 <sup>a</sup>	NS	7-day PHI

TABLE A. continued

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
<b>Grape</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	1.5	NS	NS	14-day PHI for rates >1 lb ai/A 7-day PHI for rates ≤ 1 lb ai/A  In CA the restricted entry interval (REI) is 5 days
	5% D [10163-168]	1.5	NS	NS	7-day PHI CA only
<b>Kiwifruit</b>					
Broadcast foliar ground, aerial equipment	50% WP [CA790058]	2.0	6	NS	21-day PHI
<b>Nectarine</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	3.0	NS	NS	14-day PHI In CA the REI is 5 days
<b>Nuts (including walnuts, filberts, and others)</b>					
Broadcast foliar ground, aerial equipment	70% WP [10163-169]	6.0	5	NS	Do not apply after hull split or within 14 days of harvest
<b>Peach</b>					

TABLE A. continued

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	3.0	4	NS	14-day PHI In CA the REI is 5 days
<b>Pears</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	5.0	NS	NS	7-day PHI
<b>Peas (Pacific Northwest only)</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	1.0	NS	NS	7-day PHI for peas 10-day PHI/PGI for forage

TABLE A. continued

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
<b>Pecans</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	2.25	NS	7	14-day PHI
<b>Pistachio</b>					
Broadcast foliar ground, aerial equipment	70% WP [10163-169]	4.0	1	N/A	7-day PHI
<b>Plum/prune</b>					
Broadcast foliar ground, aerial equipment	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	3.0	NS	NS	7-day PHI

TABLE A. continued

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
<b>Potatoes (except CA)</b>					
Broadcast foliar ground equipment chemigation	50% WP [10163-166] [10163-175] 70% WP [10163-169] [10163-184]	1.0	NS	NS	7-day PHI For machine harvested potatoes only
<b>Sweet potatoes</b>					
Broadcast plant bed ground equipment	70% WP <sup>c</sup>	0.9	5	NS	7-day PHI
Postharvest	5% D [10163-168]	0.2 oz ai/50 lb bushel	1	N/A	Wash in clean water before marketing



TABLE A. continued

Use Site Application type, timing, equipment	Formulations [EPA Reg. No.]	Maximum rate lb ai/A	Maximum # applications	Minimum re- treatment interval	Restrictions <sup>a</sup>
Livestock					
Cattle (beef and non-lactating dairy cattle)					
Spray	1 lb/gal EC [773-76]	1:100 dilution	NS	7	3-day pre-slaughter interval (PSI) Do not treat non-lactating dairy cattle within 28 days of freshening
Backrubber		1:50 dilution with diesel fuel	N/A	N/A	N/A
Swine					
Spray	1 lb/gal EC [773-76]	1:49 dilution	2	14	1-day PSI

<sup>a</sup> All of Gowan's crop use labels specify a 24-hour REI, unless otherwise stated under use restrictions.

Minimum application volumes are: for tree/vine crops, 20 gal/A by ground equipment and 5 gal/A by air; and for field crops, 5 gal/A by ground equipment and 3 gal/A by air.

<sup>b</sup> Includes EPA SLN Nos. AR920001, GA920001, IL930002, MI910007, OR920008, SC920004, WA920029.

<sup>c</sup> Includes EPA SLN Nos. AL950002, AR930007, AR950001, GA940009, GA950002, IL930005, IL950002, IL960001, MI930006, MI950002, MS960003, MS960004, OR940043, OR940044, SC950003, SC950004, WA950015, WA950016.

<sup>d</sup> Includes EPA SLN Nos. AL970001, AL970002, AR960001, AR960002, GA960003, GA960004, LA950008, MS950010, MS950011, NC950009, TN950005.

Table B. Residue Chemistry Science Assessments for Reregistration of Phosmet.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
860.1200: Directions for Use	N/A	Yes <sup>2</sup>	See Table A.
860.1300: Plant Metabolism	N/A	No <sup>3</sup>	<b>00037167 00112312</b> 41257801 <sup>4</sup> 41990101 <sup>5</sup> 42617601 <sup>6</sup> 42617701 <sup>6</sup> 42621401 <sup>6</sup> 44356001 <sup>3</sup> 44356101 <sup>3</sup> 44404801 <sup>3</sup>
860.1300: Livestock Metabolism	N/A	No <sup>7</sup>	<b>001122241</b> 42640201 <sup>8</sup> 42646801 <sup>8</sup> 44061301 <sup>9</sup> 44061302 <sup>9</sup>
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	<b>00037165 00037166</b> <b>00037168 00056849</b> <b>00056852 00056862</b> <b>00067069 00078567</b> <b>00084808 00087762</b> <b>00095485 00112241</b> <b>00112262 00112265</b> <b>00112274 00112296</b> <b>00112313 05004211</b> 40999001 <sup>10</sup>
- Livestock commodities	N/A	No	<b>000112241</b> 44244401 <sup>11</sup> 44281101 <sup>11</sup>
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability Data	N/A	Yes <sup>12</sup>	<b>00056850 00056851</b> <b>00084815 00097846</b> <b>00112279</b> 41100701 41211401 43556301 <sup>13</sup> 43556302 <sup>13</sup>
860.1500: Crop Field Trials			
<u>Root and Tuber Vegetables Group</u>			
- Potato	0.1 [§180.261 (a)]	No	<b>00094636 00112260</b> <b>00112271 00116855</b> 43412501 <sup>14</sup>
- Sweet potato	10 [§180.261 (a)]	Yes <sup>15</sup>	<b>000112262</b> 41000401 44505501 <sup>16</sup>

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Peas succulent and dried	0.5 [§180.261 (a)]	No	<b>00084814</b> 43536601 <sup>10</sup>
<u>Foliage of Legume Vegetables Group</u>			
- Peas forage	10 [§180.261 (a)]	No	<b>00061721 00084814</b> <b>00112283</b> 43536601 <sup>10</sup>
- Peas forage	10 [§180.261 (a)]	No	<b>00061721 00084814</b> <b>00112283</b> 43536601 <sup>10</sup>
<u>Fruiting Vegetables (Except Cucurbits) Group</u>			
- Tomato	2.0 [§180.261 (a)]	No	<b>00081616</b>
<u>Citrus Fruits Group</u>	5.0 [§180.261 (a)]	No	<b>00084810 00112283</b>
<u>Pome Fruits Group</u>			
- Apple	10.0 [§180.261 (a)]	No	<b>00044198 00056854</b> <b>00056858 00093486</b> <b>00106602 00112302</b>
- Crabapple	20.0 [§180.261 (b)]	No	40557401 <sup>17</sup>
- Pear	10.0 [§180.261 (a)]	No	<b>00093486 00116602</b>
<u>Stone Fruits Group</u>			
- Apricot	5.0 [§180.261 (a)]	No	<b>00037173</b>
- Cherry	10.0 [§180.261 (a)]	No	<b>00037174</b>
- Nectarine	5.0 [§180.261 (a)]	No	<b>00037173 00093486</b>
- Peache	10.0 [§180.261 (a)]	No	<b>00037173 00056854</b> <b>00093486 00106602</b>
- Plum (fresh prune)	5.0 [§180.261 (a)]	No	<b>00037174 00093486</b> 43377501 <sup>18</sup> 43377502 <sup>17</sup>
<u>Berries Group</u>			
- Blueberry (huckleberry)	10.0 [§180.261 (a)]	Yes <sup>19</sup>	<b>00084809</b> 41971301 <sup>20</sup>
<u>Tree Nuts Group</u>			
- Almond, hulls	10.0 [§180.261 (a)]	No	<b>00044198 00056814</b> <b>00056858 000848130</b> <b>0093468</b>
- Nuts	0.1 [§180.261 (a)]	No	43536901 <sup>21</sup>

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
<u>Cereal Grains Group</u>			
- Corn, grain	0.5 [§180.261 (a)]	No	<b>00084811 00112283</b>
- Corn, sweet (K+CWHR)	0.5 [§180.261 (a)]	No	<b>00084811 00112283</b>
<u>Forage Fodder and Straw of Cereal Grains</u>			
- Corn forage and fodder	10.0 [§180.261 (a)]	No	<b>00037157 00084811</b>
<u>Non-grass Animal Feeds</u>			
- Alfalfa	40.0 [§180.261 (a)]	No	<b>00056858 00095485</b>
<u>Miscellaneous Commodities</u>			
- Cottonseed	0.1 [§180.261 (a)]	No	<b>00067068 00112245</b> <b>00112281 40111101</b>
- Cotton, gin byproducts	None	Yes <sup>22</sup>	
- Cranberry	10.0 [§180.261 (a)]	Yes <sup>23</sup>	<b>00084812 00112283</b>
- Grape	10.0 [§180.261 (a)]	No	<b>00037175 00112247</b>
- Kiwifruit	25.0 [§180.261 (a)]	No	<b>00112279</b>
- Pistachio	0.1 [§180.261 (b)]	No	00160755 <sup>24</sup>
860.1520: Processed Food/Feed			
- Apple	None	No	41840401 <sup>25</sup>
- Citrus	None	No	
- Cottonseed	None	No	40111101
- Grape	None	No	43391801 <sup>26</sup>
- Plum/prune	None	No	43391802 <sup>25</sup>
- Potato	None	No	43401301 <sup>10</sup>
- Tomato	None	No	
860.1480: Meat Milk Poultry Eggs			
- Fat, Meat and Meat Byproducts of Cattle Goats Hogs Horses and Sheep	0.2 [§180.261 (a)]	No	<b>00037155 00037161</b> <b>00037162 00056860</b> <b>00078568 00078570</b> <b>00112249 00112316</b> <b>00112325 05012698</b> 44244401 <sup>11</sup> 44281101 <sup>11</sup>
- Milk	None	No <sup>27</sup>	<b>05012698</b>
- Eggs and the Fat Meat and Meat Byproducts of Poultry	None	No	<b>00112310</b>

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
860.1400: Water Fish and Irrigated Crops	None	No	
860.1460: Food Handling	None	No	
860.1850: Confined Rotational Crops	N/A	No <sup>28</sup>	42837901 <sup>29</sup> 44356201 <sup>29</sup>
860.1900: Field Rotational Crops	None	No	

1. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Phosmet Reregistration Standard Guidance Document dated 9/86; non-bolded references were reviewed in the Residue Chemistry Chapter of the Phosmet Reregistration Standard Update dated 3/8/90. All other references were reviewed as noted.
2. Based upon the available residue data and/or changes in data requirements, the Agency is recommending changes to label directions for uses on certain crops. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under Directions for Use or in Table B under each crop.

The registrant must add a 30-day crop rotation interval (for all crops) to phosmet labels.

For cattle, the Del-Phos® label should be amended to specify a maximum of four applications to cattle at a minimum 7-day re-treatment interval.

3. DP Barcode Nos. D238666 and D240710, 3/2/98, C. Swartz.
4. CBRS Nos. 6988 and 7000, DP Barcode D154947, 4/16/91, R. Perfetti.
5. CBRS No. 8539, DP Barcode D168334, 4/21/92, E. Zager.
6. CBRS No. 11243, DP Barcode D187122, 4/6/93, S. Knizner.
7. DP Barcode No. D232967, 11/7/97, C. Swartz.
8. CBRS Nos. 11326/11399, DP Barcodes D187836/D188337, 9/24/93, R. Perfetti.
9. CBRS No. 17454, DP Barcode D228266, 7/22/97, C. Swartz.
10. DP Barcodes D201834, D201850, D201897, D222699, D230147, 7/22/97, C. Swartz.
11. DP Barcode No. D235145, 10/17/97, C. Swartz; DP Barcode No. D239151, 10/10/97, C. Swartz.
12. Additional storage stability studies should be conducted for phosmet oxon using an oil seed or nut matrix, a starchy vegetable, and a forage crop. In addition, the registrant must submit storage conditions and intervals incurred in the livestock feeding study submitted under MRID No. 00078570.

Table B (*continued*).

13. CBRS No. 15265, DP Barcode D213100, 4/18/95, S. Funk.
14. DP Barcode No. D209734, 9/15/97, D. Hrdy.
15. A study submitted in support of the post-harvest application to sweet potatoes has been deemed inadequate due to significant GLP violations. Additional data are required depicting phosmet residues in/on unwashed sweet potatoes following post-harvest treatment with the 5% D formulation at 0.2 oz ai/50 lb bushel. Residue trials must be conducted in different storage facilities and must reflect typical storage conditions. The sampling method must be described and residues must be determined using validated analytical methodology.  
  
There are numerous 24(c) labels bearing plant-bed use on sweet potatoes, representing the major U.S. production regions. HED has determined that the existing data on potatoes can be translated to support this use. Therefore, the plant bed use should be added to the Federal labels and the 24(c) uses should be canceled.
16. DP Barcode No. D244248, under review in HED.
17. CBRS Nos. 3592 and 4031, no DP Barcode, PP#8E3621, 3/2/88 and 5/6/88, S. Willett.
18. CBRS No. 15004, DP Barcode D210876, 1/02/96, S. Funk.
19. Additional residue data for blueberry are required to achieve adequate geographic representation. Additional trials must be conducted in MI (3 trials), NC, and WA or OR (D165336, 07/25/91, R. Lascola; and CBRS No. 9889, DP Barcode D178401, 7/22/92, S. Hummel).
20. D168053, 10/24/91, R. Lascola.
21. CBRS No. 15266, DP Barcode D213104, 4/20/95, S. Funk.
22. Based on OPPTS Guidelines, data are required depicting phosmet and phosmet oxon residues in cotton gin byproducts ginned from cotton harvested 21 days after the last of three foliar applications each at 1 lb ai/A. The cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue from the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials.
23. A proposed amended use on cranberry is currently under review.
24. CBRS Nos. 2505 and 2602, no DP Barcode, PP#6E3425, 8/11/87, S. Malak.
25. DP Barcode D165066, 4/7/92, P. Deschamp.
- 26.. CBRS No. 15268, DP Barcode D213103, 5/2/95, S. Funk.
27. Provided the registrant does not object to a tolerance of 0.1 ppm for the combined residues of phosmet and its oxon in milk, no additional data are required. If the registrant intends to demonstrate that residues in milk may be classified under Category 3 of 40 CFR §180.6(a), a new dairy cattle feeding study will be required, with concomitant milk residue data.
28. DP Barcode No. D238665, 10/10/97, C. Swartz.

### TOLERANCE REASSESSMENT SUMMARY

Tolerances for phosmet residues are expressed in terms of phosmet and its oxygen analog [40 CFR §180.261 (a) and (b)]. A summary of the phosmet tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

#### Tolerances Listed Under 40 CFR §180.261 (a) and (b):

Provided that the requested label amendments are made, sufficient data are available to assess tolerances for phosmet residues in alfalfa, almond hulls, apple, cherry, cottonseed, grape, kiwifruit, nectarine, peach, pea, pistachio, plum, potato, and nut crops.

The tolerance for residues in alfalfa should be revised to specify alfalfa forage (with a separate tolerance to be established for residues in alfalfa hay); the tolerance for residues in alfalfa forage may be reduced to 20 ppm, as per the 1986 Reg. Std. The tolerance for residues in peas should be revised to specify peas, dry (with a separate tolerance to be established for residues in succulent peas).

Should the registrant wish to reinstate a use on sweet corn, sufficient data may be available to support the established tolerances (1986 Residue Chemistry Chapter). If the sweet corn use is reinstated, the established tolerance for residues in corn fodder should be revised to reflect the correct commodity definition, corn stover.

Additional residue data are required before tolerances can be reassessed on the following commodities: blueberry and sweet potato. Should the registrant wish to reinstate a use on citrus fruit, additional grapefruit residue data may be required. The tolerance for residues in cranberry is not being reassessed at this time since a proposed use is currently under review. Tolerances for residues in commodities from field corn and tomatoes should be revoked, since there are no registered uses on these crops. The registrant may wish to retain use on citrus fruits and sweet corn, pending review of use patterns and available data.

Established tolerances for residues in livestock commodities have been reassessed based on the reassessed tolerances in livestock feed items, and on available feeding studies and dermal application studies. The tolerances for residues in meat and meat by-products of cattle, goats, horses and sheep are reassessed at 0.1 ppm; the tolerance for residues in fat of cattle is reassessed at 0.2 ppm. The tolerance for residues in fat of goats, horses and sheep is recommended to be 0.1 ppm; a lower tolerance is appropriate since there are no dermal applications registered for goats, horses and sheep.

Tolerances Needed Under 40 CFR §180.261:

When the required residue data are submitted, a tolerance for phosmet residues in cotton gin byproducts should be established. As stated above, separate tolerances must be established for residues in alfalfa forage and alfalfa hay, and for residues in succulent peas at [1.0 ppm].

A tolerance is needed for residues in cottonseed oil; 0.2 ppm is an appropriate tolerance level.

A tolerance of 0.1 ppm should be established for phosmet residues in milk; the registrant may want to submit a new ruminant feeding study to demonstrate that residues in milk could be classified under category 3 or 40 CFR §180.6(a).



Table C. Tolerance Reassessment Summary for phosmet.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
<b>Tolerances Listed under 40 CFR §180.261 (a)</b>			
Alfalfa	40	20	A separate tolerance is needed for residues in alfalfa hay/ <i>alfalfa, forage</i>
Almond, Hulls	10	10	
Apple	10	10	
Apricot	5	5	
Blueberry	10	TBD <sup>a</sup>	
Cattle, Fat	0.2	0.2	
Cattle, MBYP	0.2	0.1	
Cattle, Meat	0.2	0.1	
Cherry	10	10	
Citrus Fruits	5	Revoke <sup>b</sup>	No registered use
Corn, Fodder	10	Revoke <sup>c</sup>	No registered use
Corn, Forage	10	Revoke <sup>c</sup>	No registered use
Corn, Sweet (K+CWHR)	0.5	Revoke <sup>c</sup>	No registered use
Corn, Grain	0.5	Revoke	No registered use
Cotton, Seed	0.1	0.1	<i>Cotton, seed, undelinted</i>
Cranberry	10	TBD	A proposed use is under review
Goats, Fat	0.2	0.1	
Goats, MBYP	0.2	0.1	
Goats, Meat	0.2	0.1	
Grape	10	10	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Hogs, Fat	0.2	0.2	Revised tolerances are based on dermal treatment.
Hogs, MBYP	0.2	0.04	
Hogs, Meat	0.2	0.04	
Horses, Fat	0.2	0.1	
Horses, MBYP	0.2	0.1	
Horses, Meat	0.2	0.1	
Kiwifruit	25	25	
Nectarine	5	5	
Nut	0.1	0.1	<i>Tree Nuts and Pistachio</i>
Peach	10	10	
Pear	10	10	
Pea	0.5	0.5	Separate tolerances are needed for residues in dry and succulent pea/ <i>pea, dry</i>
Pea, Forage	10	10	<i>Pea, field, vines</i>
Pea, Hay	10	20	<i>Pea, field, hay</i>
Plum (Fresh Prune)	5.0	5.0	
Potato	0.1	0.1	
Sheep, Fat	0.2	0.1	
Sheep, MBYP	0.2	0.1	
Sheep, Meat	0.2	0.1	
Sweet Potato (Post-H)	10	TBD	
Tomato	2	Revoke	No registered use

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
<b>Tolerances Listed under 40 CFR §180.261 (b)</b>			
Crabapple (Post-H)	20	20	<i>Crabapple</i>
Pistachio	0.1	Revoke	See Comment under Nut
<b>Tolerances Needed under 40 CFR §180.261</b>			
Alfalfa, hay	[Currently covered by "alfalfa"]	40	
Cotton gin byproducts	None	TBD	
Cotton seed, refined oil	None	0.2	
Pea, succulent	[Currently covered by "peas"]	1	
Milk	None	0.1	Based on the combined limits of quantitation (LOQs) for phosmet and phosmet oxon

- <sup>a</sup> TBD = To be determined; additional residue data are required or amended uses are under review.
- <sup>b</sup> If the registrant wishes to reinstate a use on citrus fruit, additional grapefruit residue data may required, depending on the use pattern.
- <sup>c</sup> If the registrant wishes to reinstate a use on sweet corn, adequate data may be available; the existing data will be re-evaluated. The commodity listing for corn fodder should be changed to "corn stover."

### CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for phosmet residues in various plant commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex MRLs for phosmet are currently expressed in terms of the parent and oxygen analog; thus, the U.S. tolerance definition is compatible with the Codex MRLs. A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table D.

Table D. Codex MRLs for Phosmet and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Alfalfa fodder	40	CXL	40	Compatible
Alfalfa forage (green)	40	CXL	20	
Apple	10	CXL	10	Compatible
Apricot	5	CXL	5	Compatible
Blueberry	10	CXL	TBD <sup>b</sup>	
Cattle meat	1	CXL	0.1	
Citrus fruits	5	CXL	To be revoked	
Feijoa	2	CXL	None	
Grape	10	CXL	10	Compatible
Kiwifruit	15	CXL	25	
Maize	0.05	CXL	To be revoked	
Maize fodder	10	CXL	To be revoked	
Maize forage	10	CXL	To be revoked	
Milks	0.02 <sup>a</sup>	CXL	0.1	To be established based on LOQ for phosmet and oxon.
Nectarine	5	CXL	5	Compatible
Pea hay or pea fodder (dry)	10	CXL	20	The U.S. tolerance cannot be reduced, given the current use pattern
Pea vines (green)	10	CXL	10	Compatible
Peach	10	CXL	10	Compatible
Pear	10	CXL	10	Compatible
Peas (dry)	0.02 <sup>*</sup>	CXL	0.5	
Peas (pods and succulent = immature seeds)	0.2	CXL	1	
Potato	0.05	CXL	0.1	Compatible
Sweet corn (corn-on-the-cob)	0.05	CXL	To be revoked	
Sweet potato	10	CXL	TBD	
Tree nuts	0.1	CXL	0.1	Compatible

<sup>a</sup> An asterisk (\*) signifies that the MRL was established at or about the limit of detection.

<sup>b</sup> TBD = To be determined; additional data are required before the U.S. tolerance can be determined.

## DIETARY EXPOSURE SUMMARY

The available residue data are adequate for the purpose of determining dietary exposure for use in Agency risk assessments for phosmet. Anticipated residues for risk assessment are being developed for numerous raw agricultural commodities and milk by HED/CEB2, and are not included herein. These anticipated residues are based on percent crop treated data calculated by BEAD (Quantitative Usage Analysis dated 3/5/98, Jihad A. Alsadek) and monitoring data provided by USDA's Pesticide Data Program (PDP). Therefore, the anticipated residues for most crops are considered to be realistic, and not worst-case.

Anticipated residues in meat, meat byproducts and fat are calculated herein, based on the theoretical diets discussed above, average residues in alfalfa forage field trials, and percent crop treated (%CT) data generated by BEAD, indicating <1% crop treated for alfalfa.

Based on alfalfa field trial data submitted under MRID Nos. 00056858 and 00095485, there are 17 data points for alfalfa forage reflecting a 1X rate (for states other than NV, CA and AZ) with a 7-day PHI; an additional 2 data points reflect a 0.5X rate, with a 7-day PHI. These residue values were doubled and included in the average field trial residue for forage. An additional 2 data points are available from a CA field trial reflecting a 2.9X application and a 14-day PHI. These residue values were adjusted to a 1X application rate, and included in the average residue. The average combined phosmet and phosmet oxon residue in alfalfa forage is 3.6 ppm. When corrected for %CT (<1%), the anticipated residue in alfalfa forage is 0.036 ppm. The anticipated dietary burden, based on an alfalfa forage AR of 0.036 ppm, and on tolerance-level residues in cottonseed and peas, is calculated as follows:

Feed Commodity	% Dry Matter <sup>a</sup>	% Diet <sup>a</sup>	Anticipated Residue (ppm) <sup>b</sup>	Dietary Contribution (ppm) <sup>c</sup>
<b>Beef Cattle</b>				
Alfalfa forage	35	70	0.036	0.072
Cotton, seed	88	10	0.1 (Tol.)	0.01
Pea seed	90	20	0.5 (Tol.)	0.11
<b>TOTAL BURDEN</b>		100		<b>0.192</b>

<sup>a</sup> Table 1, OPPTS GLN 860.1000.

<sup>b</sup> Reassessed tolerances from Table C for cottonseed and pea seed; anticipated residue calculated for alfalfa (see above).

<sup>c</sup> Contribution = [tolerance or AR/ %DM (if cattle)] X % diet).

The anticipated dietary burden to beef cattle is 0.005X the maximum theoretical dietary burden used to determine tolerances for phosmet residues in meat, meat by-products and fat. The dosing levels used in the cattle feeding study correspond to 104X/1042X, 234X and 521X the anticipated dietary burden. For the purpose of calculating anticipated residues, only the 45 ppm and 100 ppm dosing levels are to be used, since the 20 ppm dosing level was increased to 200 ppm after 2

weeks. Residues in tissues at these 2 dosing levels were adjusted to 1X, and the tissue values averaged. Since apparent liver values were reported to be 0 ppm, a default value of ½LOQ is used in the current analysis. Using feeding study results (refer to residues in meat/milk/poultry/eggs section of this document) and on an anticipated dietary burden of 0.192 ppm, anticipated residues [due to consumption of feed items containing phosmet residues] in meat, meat byproducts and fat are calculated to be 0.000085, 0.00006 and 0.00017 ppm, respectively.

Based on the results of the dermal treatment study, anticipated residues in meat, meat byproducts and fat resulting from dermal application are 0.024, 0.02, and 0.026 ppm, respectively. Since anticipated residues based on consumption of treated feed items are negligible when compared with those resulting from dermal application, for the purpose of dietary risk assessment, anticipated residues in cattle are to be based solely on dermal residues. The anticipated residues determined based on consumption of treated feed items should be used for goats, horses and sheep.

#### AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No.: 2505/2602  
DP Barcode: None  
Subject: Phosmet on pistachios. PP#6E3425  
From: S. M.  
To: N/A  
Date: 8/11/87  
MRID(s): 00160755

CBRS No.: 3592/4031  
DP Barcode: None  
Subject: Phosmet on crabapples. PP#8E3621  
From: S. W.  
To: N/A  
Date: 5/6/88  
MRID(s): 40557401

CBRS No.: 6988/7000  
DP Barcode: D154947  
Subject: Response to Phosmet Reregistration Standard: Plant Metabolism Study  
From: R. Perfetti  
To: R. Englar  
Date: 4/16/91  
MRID(s): 41257801

CBRS No.: 8151  
DP Barcode: D165336  
Subject: Phosmet on blueberries. Amendment of 8/2/91  
From: R. Lascola  
To: P. Errico  
Date: 07/25/91  
MRID(s): 41791301

CBRS No.: 8539  
DP Barcode: D168334  
Subject: Phosmet. Registrant's Response to Residue Chemistry Data Requirements:  
Cherry Metabolism Study.  
From: E. Zager  
To: L. Rossi  
Date: 4/15/92  
MRID(s): 41990101

CBRS No.: 8133  
DP Barcode: D165066  
Subject: Phosmet in apple and peach processed commodities  
From: P. Deschamp  
To: L. Rossi  
Date: 4/7/92  
MRID(s): 41840401

CBRS No.: 11243  
DP Barcode: D187122  
Subject: Guideline 171-4(a) Nature of the Residue in Cherries, Corn and Potatoes.  
From: S. Knizner  
To: B. Lowery  
Date: 4/6/93  
MRID(s): 42621401, 42617701, 42617601

CBTS No.: 12274  
DP Barcode: D193413  
Subject: Review of confined rotational crop study of phosmet  
From: G. Kramer  
To: L. Schnaubelt  
Date: 9/1/93

MRID(s): 42837901

CBRS No.: 11326 and 11399

DP Barcode: D187836 and D188337

Subject: Response to the Phosmet Reregistration Standard: Livestock Metabolism

From: R. Perfetti

To: L. Rossi

Date: 9/24/93

MRID(s): 42646801 and 42640201

CBRS No.: 15265

DP Barcode: D213100

Subject: Phosmet. Storage Stability for Peaches, Apples, and Their Processed Commodities.

From: S. Funk

To: L. Schnaubelt

Date: 4/18/95

MRID(s): 43556301 and 43556302

CBRS No.: 15266

DP Barcode: D213104

Subject: Phosmet. Magnitude of the Residue in/on Walnuts

From: S. Funk

To: L. Schnaubelt

Date: 4/20/95

MRID(s): 43536901

CBRS No.: 15268

DP Barcode: D213103

Subject: Phosmet. Grape and Plum Processing Studies.

From: S. Funk

To: L. Schnaubelt

Date: 5/2/95

MRID(s): 43391801 and 43391802

CBRS No.: None

DP Barcode: None

Subject: Phosmet. HED Metabolism Committee Update on Concern for Phthalimide Metabolite.

From: M. Metzger



To: HED Metabolism Committee  
Date: 8/11/95  
MRID(s): None

CBRS No.: 15004  
DP Barcode: D210876  
Subject: Phosmet. Plum Field Trial Studies (GLN 171-4(k)). Plum Processing Study Revisited (GLN 171-4(l)). Residue Chemistry Data Requirements Revisions.  
From: S. Funk  
To: L. Schnaubelt  
Date: 1/2/96  
MRID(s): 43377501 and 43377502

CBTS Nos.: 13569/13570/13571; CBRS Nos. 16875/17566  
DP Barcode: D201834/D201850/D201897/D222699/230147  
Subject: Phosmet. Guideline Nos. 860.1500 and 860.1520. Magnitude of the Residue in Succulent/Dry Peas; Magnitude of the Residue in Processed Potato Commodities; Magnitude of the Residue in Plums; Proposed Label Amendments.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 7/22/97  
MRID(s): 43536601, 43401301, and 44099901

CBRS No.: 17454  
DP Barcode: D228266  
Subject: Phosmet. Guideline No. 860.1300. Dermal Metabolism Studies on Cattle and Swine.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 7/22/97  
MRID(s): 44063101 and 44061302

CBRS No.: None.  
DP Barcode: D239151  
Subject: Phosmet. Magnitude of the residue in cattle following dermal application.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 10/10/97  
MRID(s): 44281101

CBRS No.: None  
DP Barcode: D235145  
Subject: Phosmet. Magnitude of the residue in swine following dermal application.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 10/17/97  
MRID(s): 44244401

CBRS No.: None  
DP Barcode: D238127.  
Subject: Phosmet. Guideline Ref. No. 860.1380. Gowan's submission of storage stability data to support grape and dry pea residue studies.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 11/7/97  
MRID(s): 44335601

CBRS No.: None  
DP Barcode: D232967  
Subject: Phosmet. Guideline No. 860.1300: nature of the residue in ruminants. Gowan's response to HED review.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 11/7/97  
MRID(s): None

CBRS No.: None  
DP Barcodes: D238666 and D240710  
Subject: Phosmet. Guideline No. 860.1300: Plant metabolism. Gowan's submission to upgrade corn and potato studies. Guideline No. 860.1340/1380: Residue method validation and storage stability data for corn commodities.  
From: C. Swartz  
To: L. Werrell/K. Monk  
Date: 3/2/98  
MRID(s): 44356001, 44356101 and 44404801

CBRS No.: None  
DP Barcodes: D245052  
Subject: Phosmet. Guideline No. 860.1380: Storage stability data to support dermal magnitude of the residue studies in cattle and swine.  
From: C. Swartz

To: L. Werrell/K. Monk  
Date: 9/17/98  
MRID(s): MRID Nos. 445235-01 through -04

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